LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Serefarm
(salmeterol xinafoate, fluticasone propionate)

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Inhalation powder, pre-dispensed, 50 microgram/100 microgram/dose,
50 microgram/250 microgram/dose, 50 microgram/500 microgram/dose

This is a summary of the public assessment report (PAR) for Serefarm. It explains how the assessment was made and why the authorisation was recommended as well as the conditions of use. It is not intended to provide practical advice on how to use the product.

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

What is Serefarm and what is it used for?

The product is a 'hybrid medicine'. This means that it is similar to a reference medicine containing the same active substance.

The reference medicines for the product are Seretide Diskus mite, Seretide Diskus and Seretide Diskus forte, respectively.

The company has provided additional own data to demonstrate therapeutic equivalence between the product and the reference medicines.

The product is used in the treatment of
• Asthma.
• Chronic Obstructive Pulmonary Disease (COPD). Serefarm, at a dose of 50/500 micrograms, reduces the number of flare ups of COPD symptoms.

How does Serefarm work?

Serefarm contains two medicines, salmeterol and fluticasone propionate:
- Salmeterol is a long-acting bronchodilator. Bronchodilators help the airways in the lungs to stay open. This makes it easier for air to get in and out. The effects last for at least 12 hours.
- Fluticasone propionate is a corticosteroid which reduces swelling and irritation in the lungs.

How is Serefarm used?

The pharmaceutical form is inhalation powder, pre-dispensed for inhalation use.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription in Sweden.

What benefits of Serefarm have been shown in studies?

Because the product is a hybrid application and is considered to be therapeutically equivalent to the reference products, the benefits and risks are taken as being the same as those of the reference medicines.

What are the possible side effects from Serefarm?

For the full list of side effects, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Serefarm approved?

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered to be therapeutically equivalent to the reference medicines. Therefore, the Swedish Medical Products Agency decided that, as for the reference medicines, the benefits are greater than its risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Serefarm?

A risk management plan has been developed to ensure that the product is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Serefarm

The full PAR for Serefarm can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Serefarm, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2022-09.